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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,108	06/18/2001	Jane Dixon	3875-4138US	6832

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EXAMINER	
PAK, MICHAEL D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,108	DIXON ET AL.	
	Examiner	Art Unit	
	Michael Pak	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *2,3,8,9,15-20,22,23,28-31,33,34,39-42 and 50-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7,10-14,21,24-27,32,35-38 and 43-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2-26-02; 3-17-03; 11-21-02*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group I in the reply filed on 12 July 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 2, 3, 8, 9, 15-20, 22, 23, 28-31, 33-34, 39-42 and 50-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12 July 2004.

Claim Rejections - 35 USC § 101 and 35 USC § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 4-7, 10-14, 21, 24-27, 32, 35-38, 43-49 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

A "specific utility" is a utility that is specific to the subject matter claimed, as opposed to a "general utility" that would be applicable to the broad class of the invention. A "substantial utility" is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. A "well established utility" is a utility that is well known, immediately apparent, or implied by the specifications disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. A "well established utility" must also be specific and substantial.

Based on the record, there is not a "well established utility" for the claimed invention. The specification has asserted utilities for the specifically claimed invention of claims 1, 4-7, 10-14, 21, 24-27, 32, 35-38, 43-49. For example, the specification at page 5 asserts that, the present invention provides sequences for novel Eag-like potassium channel subunit, and knowledge of the polypeptides encoded by the claimed invention permits the localization. Cells expressing the polypeptide may be used ensure compounds identified for use as drugs for other diseases do not have a deleterious effect on the function of the potassium channels as stated on page 9 of the specification. Since defects in the novel potassium channel subunits may be associated with a human genetic diseases listed on page 18.

The asserted utilities are not specific or substantial. Neither the specification nor the art of record disclose any disease states treatable by the claimed polynucleotides or its encoded polypeptide. Similarly, neither the specification nor the

art of record disclose any instances where blocking any effects of the claimed polynucleotide or its encoded polypeptide reduces the effect of a disease state. Thus the corresponding asserted utilities are essentially methods of treating unspecified, undisclosed diseases or conditions, which does not define a "real world" context of use. Treating an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use such as identifying a disease with the mutation in the claimed gene sequence. Since neither the specification nor the art of record disclose any activities or properties that would constitute a "real world" context of use for the claimed polynucleotide or its encoded polypeptide, further experimentation is necessary to attribute a utility to the claimed invention. See Brenner v. Manson, 383 U.S. 519, 535B36, 148 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing", and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

Although the complete α1 subunits of potassium channel, alone, can form functional channels, as stated on page 9, the fact that their electrophysiological and pharmacological properties can be differently modulated by co expression with any of the four β subunits argues that effects of potassium channel modulation will vary in the native state depending on the availability of four β subunits. The possibility exists that other subunits, in addition to the ones known may have to be discovered which are required to confer functionality on the claimed α1 subunit, which is required for its

physiological function. The specification nor prior art disclose any ligands, agonists or antagonists that bind or affect the functionality of the claimed DNA encoding the α1 subunit of the claimed channel protein. Further the specification, on page 18, discloses, a list of possible diseases, associated with claimed potasssium channels. However, defective forms are not disclosed. There is no disclosure of any specific disease states associated with dysfunction of claimed DNA (SEQ ID NO:2) encoding the α1 subunit of a potassium channel protein or defective forms of said protein or polynucleotide. The specification does not disclose a correlation between any specific disorder and an altered level or form of the claimed polynucleotides. Also, the specification does not predict whether the claimed polynucleotides would be over expressed or under expressed in a specific, diseased tissue compared to the healthy tissue control. Further, the specification does not predict whether the claimed polynucleotide encodes a polypeptide that increases or decreases ion flux in a specific, diseased tissue compared to the healthy tissue control. For example, if a compound is tested on an assay comprising the claimed polynucleotides and affects expression of the polynucleotide negatively, it cannot be determined if that means that the compound is a potential good drug for a disease or would acerbate the disease if administered. Similarly it cannot be determined if agonist or antagonist to the polypeptide encoded by SEQ ID NO:2 is a potential good drug for a disease or would acerbate the disease if administered.

There are no known agonists for the claimed potassium channel therefore the effect of antagonists cannot be determined. Applicant has not disclosed any

antagonists or agonists that bind to the protein encoded by claimed DNA that may be used to treat conditions associated with potassium channels or any specific disease states or dysfunctions treatable with said agonists and antagonists. Without knowledge of the functionality of the claimed invention, it is not clear, how one can make the assumption that an antagonist will treat a specific condition. Dysfunction of a potassium channel may be caused by increased or decreased channel activity, therefore a conclusion that an antagonist will treat a disease state is incorrect, the agonist may be required.

The complex nature of potassium signaling, the diversity of the effects of potassium in signaling mechanisms and the effects of the various potassium channels in signaling mechanisms is dependent on the specific potasium channel. The entry of potassium into cells mediates a wide variety of cellular and physiological responses including excitation-contraction coupling, hormone secretion and gene expression (specification, pages 1-2). Since all potassium channels are not involved with the same disease state, and electrophysiological and pharmacological properties can be differently modulated by the β subunits, the cell environment and the effects of potassium channel modulation will vary with cell type and specific potasium channel protein. Therefore an association between the claimed potassium channel and an associated dysfunction cannot be made based on the specification and prior art. The specific physiological function of the ion channel of SEQ ID NO:2 has not been disclosed.

Pertaining to the use of claimed invention as biological target for screening libraries of compounds as candidate pharmaceuticals. As disclosed above the potassium channels have diverse effects. Applicant has not disclosed any specific disease state involve in dysfunction of claimed invention. The instant application does not disclose the biological role of the polypeptide of SEQ ID NO:2 or its significance.

These utilities are not considered to be specific and substantial because the specification fails to disclose any particular function or biological significance for the claimed polynucleotide. The disclosed protein, whose cDNA has been isolated, is said to have a potential function based upon its amino acid sequence similarity to other known proteins. After further research, a specific and substantial credible utility might be found for the claimed polynucleotide. This further characterization, however, is part of the act of invention and until it has been undertaken, applicant's claimed invention is incomplete.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are Auseful≅ to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of Auseful≅ as it appears in 35 U.S.C. ∋101, which requires that an

invention must have either an immediately apparent or fully disclosed Areal world≅ utility. The court held that:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are drawn to a polynucleotide encoding a polypeptide of as yet undetermined function or biological significance. There is no evidence of record or any line of reasoning that would support a conclusion that the claimed polynucleotide was, as of the filing date, useful for diagnosis, prevention and treatment of a disease, or for screening compounds. Until some actual and specific significance can be attributed to the polypeptide of SEQ ID NO:2, or the gene encoding said polynpeptide, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent or "real world" utility as of the filing date.

The DNA of the instant invention and the protein encoded thereby are compounds which share some structural similarity to potassium ion channels based on sequence similarity. As disclosed by the specification the family of potassium proteins may have diverse effects, and play roles in the pathogenesis of various diseases, require other subunits for binding of ligands Although the family of ion channel proteins having potassium channel protein like domains may share some common structural motifs, various members of the family may have different sites of action and different

biological effects. In the absence of knowledge of the ligand for claimed invention, or the biological significance of this protein, there is no immediately evident patentable use. To employ the polynucleotide encoding SEQ ID NO:2 or its encoded polypeptide in any of the disclosed methods would clearly be using it as the object of further research. Such a use has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for claimed polynucleotide, then the claimed invention as disclosed, does not meet the requirements of 35 U.S.C. 101 as being useful.

The specification nor claims disclose what is the critical structure of the invention that is required for functionality. For a utility to be "well-established" it must be specific, substantial and credible. All nucleic acids and genes are in some combination useful in drug screening and toxicology testing. However, the particulars of drug screening and toxicology testing with respect to polynucleotide encoding SEQ ID NO:2 are not disclosed in the instant specification. The toxic substances, agonists, antagonists and the susceptible organ systems are identified. Therefore, this is a utility which would apply to virtually every member of a general class of materials, such as any collection of proteins or DNA, but is only potential with respect to the polypeptide of SEQ ID NO:2. Because of this, such a utility is not specific and does not constitute a Awell-established≅ utility. Further, because any potential diagnostic utility is not yet known and has not yet been disclosed, the utility is not substantial because it is not currently available in practical form. Moreover, use of the claimed polynucleotide in an array for toxicology or drug screening is only useful in the sense that the information that is

gained from the array and is dependent on the pattern derived from the array, and says nothing with regard to individual member tested. Again, this is a utility which would apply to virtually ever member of a general class of materials, such as any collection of proteins or DNA. Even if the expression of Appellants, individual polynucleotide is affected by a test compound in an array for drug screening, the specification does not disclose any specific and substantial interpretation for the result, and none is known in the art. Given this consideration, the individually claimed polynucleotide has no "well-established" use. The artisan is required to perform further experimentation on the claimed material itself in order to determine to what "use" any expression information regarding this nucleic acid could be put.

With regard to diagnosis of disease, there is no requirement that each and every class of DNA sequences or the proteins they encode have an established correlation with a particular disease. However, in order for a polynucleotide or protein to be useful, as asserted, for diagnosis of a disease, there must be a well-established or disclosed correlation or relationship between the claimed polynucleotide and a disease or disorder. For example, the presence of a polynucleotide in tissue that is derived from cancer cells is not sufficient for establishing a utility in diagnosis of disease in the absence of some information regarding a correlative or causal relationship between the expression of the claimed cDNA or protein and the disease. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed polynucleotide to be used in a diagnostic manner. Many proteins are expressed in

normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed polynucleotide is either present only in cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue (i.e. over expression). Evidence of a differential expression might serve as a basis for use of the claimed polynucleotide as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder and the lack of any correlation between the claimed polynucleotide or the encoded protein with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. 101.

The polypeptide of SEQ ID NO:2 belongs to a family in which the members have divergent functions based on which tissues the protein is expressed or administered to. Assignment to this family does not support an inference of utility because the members are not known to share a common utility. There are some protein families for which assignment of a new protein in that family would convey a specific, substantial and credible utility to that protein. For example, some families of enzymes such as proteases, ligases, telomerases, etc. share activities due to the particular specific biochemical characteristics of the members of the protein family such as non-specific

substrate requirements, that are reasonably imputed to isolated compositions of any member of the family.

The diversity of the potassium channel proteins is disclosed in the specification, pages 1-4. Without some common biological activity for the family members, a new member would not have a specific, substantial, or credible utility when relying only on the fact that it has structural similarity to the other family members. The members of the family have different biological activities which may be related to tissue distribution but there is no evidence that the claimed compounds share any one of diverse number of activities. That is, no activity is known to be common to all members. To argue that all the members can be used for drug screening or toxicology testing and diagnosis, is to argue a general, nonspecific utility that would apply to virtually every member of the family, contrary to the evidence. Further, any compound could be considered as a regulator or modulator of tissue in that any compound, if administered in the proper amount, will stimulate or inhibit tissue. For example, salt, ethanol, and water are all compounds which will kill cells if administered in a great enough amount, and which would stimulate cells from which these compounds had been withheld, therefore, they could be considered regulators or modulators of tissue. However, use of these compounds for the modulation of tissue would not be considered a specific and substantial utility unless there was some disclosure of, for example, a specific and particular combination of compound/composition and application of such in some particular environment of use.

Without knowing a biological significance of the claimed polynucleotide or its encoded polypeptide, one of ordinary skill in the art would not know how to use the claimed invention in its currently available form in a "real world" manner based on the diversity of biological activities possessed by the potassium channel proteins. Contrast *Brenner*, 148 USPQ at 694 (despite similarity with adjacent homologue, there was insufficient likelihood that the steroid would have similar tumor-inhibiting characteristics), with *In re Folkers*, 145 USPQ 390, 393 (CCPA 1965) (some uses can be immediately inferred from a recital of certain properties) or *In re Brana*, 34 USPQ 1436, 1441 (Fed. Cir. 1995) (evidence of success in structurally similar compounds is relevant in determining whether one skilled in the art would believe an asserted utility; here, an implicit assertion of a tumor target was sufficiently specific to satisfy the threshold utility requirement).

The utility must be specific, substantial and credible. Applicants assertion that the claimed invention has utility in drug screening, testing, drug development and disease diagnosis, do not meet the standards for a specific, substantial, and credible or well-established utility for reasons set forth above.

The specification does not disclose the significance of any test results, nor is there any evidence that the significance was known as of the filing date. If the expression of the claimed polynucleotide increases, is this a positive or negative outcome? Would this be a toxic response or not? The disclosure is insufficient to evaluate the results of the test in any meaningful manner. Pertaining to that a utility may be specified even if it applies to a broad class of inventions. The proposition is not

sufficient to establish utility for each member of the class. Specific utility must be shown or be evident for each member of the class. None of the utilities identified have been demonstrated to be specific to the polynucleotide encoding SEQ ID NO:2 or its encoded polypeptide. One of ordinary skill in the art must understand how to achieve an immediate and practical benefit from the claimed species based on the knowledge of the class. However, no practical benefit has been shown for the use of the polypeptide of SEQ ID NO:2.

A practical utility of an invention may be derived from belonging to a broad class of inventions i.e. the practical utility can be inferred if each and every member of the broad class possesses a common utility. The specification has failed with respect to the polynuclotide encoding SEQ ID NO:2, having not described the family or the compounds in enough detail to show, by a preponderance of the evidence, that the polynuclotide encoding SEQ ID NO:2 belongs to a family that has a common utility. The record shows that the potassium channel protein family is diverse, and has such a broad definition, that a "common utility" cannot be defined. Moreover, the evidence of record is inadequate to determine the disease(s), drug(s) or toxicological screen(s) for which the compounds would be useful. In *Brenner,* the Court approved a rejection for failure to disclose any utility for a compound where the compound was undergoing screening for possible tumor-inhibiting effects and an adjacent homologue of the compound had proven effective. *Brenner*, 148 USPQ at 690. Here, there is no evidence that the claimed isolated polynucleotide has utility.

The question at issue is whether or not the broad general assertion that the claimed nucleic acids might be used for *some* diagnostic application in the absence of a disclosure of *which* diagnostic application would be considered to be an assertion of a specific, substantial, and credible utility. For reasons set forth above the disclosure satisfies none of the three criteria *See In re Kirk*, 153 USPQ 48, 53 (CCPA 1967) (quoting the Board of Patent Appeals, "We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.")

However, for reasons set forth above, Applicant has not presented sufficient evidence to support specific utility for the polynucleotide encoding SEQ ID NO:2. The present rejection under 35 USC 101 follows *Brenner v. Manson*, as set forth above. In that case, the absence of a demonstrated specific utility for the claimed steroid compound was not ameliorated by the existence of a demonstrated general utility for the class. Unlike *Fujikawa v. Wattanasin*, where there were pharmaceutically acceptable in vitro results, here, there is nothing other than relatively low levels of sequence homology to a broad and diverse family of proteins having distinct modes of activity, and no disclosed common mode of action. As Applicant recognizes, a rejection

under 35 USC 112, first paragraph, may be affirmed on the same basis as a lack of utility rejection under 35 USC 101. *See, e.g., In re Swartz*, 56 USPQ2d 1703 (Fed. Cir. 2000); *In re Kirk*, 153 USPQ 48 (CCPA 1967).

It can be argued that partial DNA sequences lack utility and that methods of identifying the full length sequence have utility i.e. identifying variants or polynucleotides comprising the polynucleotide encoding SEQ ID NO:2. The claims are directed to polynucleotides which have not been disclosed as being associated with any particular disease or condition by its being expressed at an altered level or form in diseased tissue as compared to the corresponding healthy tissue. Determining the relationship between the claimed polynucleotide or its full-length counterpart and relationship to any specific disease or disorder would require significant further research. Therefore, this asserted utility is also not substantial. The disclosed protein, whose cDNA has been isolated, is said to have a potential function based upon its amino acid sequence similarity to other known proteins. After further research, a specific and substantial credible utility might be found for the claimed polynucleotide. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicants claimed invention is incomplete. The method of identifying the full length sequence of a partial DNA sequence encoding a protein with no disclosed function also has no immediately apparent or "real world" utility as of the filing date because once the complete DNA sequence encoding said protein is isolated, further experimentation is required to associate functionality to said protein. Further, since the claimed DNA molecule or its

encoded polypeptide lack utility the methods of its use are also rejected for lack of utility for the reason given above.

3. Claims 1, 4-7, 10-14, 21, 24-27, 32, 35-38, 43-49 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substatial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

4. Claims 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12-14 recite terms "stringent hybrization", "specifically hybridizes" or "moderately stringent hybridization" which are relative terms whose conditions are not defined and the metes and bounds of the terms not clear.

Priority

5. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1, 4-7, 10-14, 21, 24-27, 32, 35-38, 43-49 of this application for the reasons provided above. See MPEP 706.02.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 4-7, 10-14, 21, 24-27, 32, 35-38, 43-49 are rejected under 35 U.S.C. 102(e) as being anticipate by Curtis et al. (US 6,518,398).

Curtis et al. disclose nucleic acid encoding SEQ ID NO:36 which has 100% amino acid sequence identity with the claimed SEQ ID NO:2 (figure 11, columns 2-6, 10-23, 32-38 and 42-47). Curtis et al. disclose vectors and isolated host cells comprising the nucleic acid (columns 32-38). Curtis et al. disclose screening assay using the host cell (columns 32-38 and 42-47).

Since the nucleic acid of Curtis et al. has regions 100% identity with the claimed nucleic acid molecule the nucleic acid of Curtis et al. will hybridize at the highest stringent conditions.

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (571) 272-0879. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-0507.

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
30 September 2004